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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TOY, ALEX B

ART UNIT PAPER NUMBER

3739

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/806,995	Applicant(s) ABBOUD ET AL.	
	Examiner Alex B. Toy	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-11, 32-36 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/2/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on March 29, 2006. The objection to the specification is withdrawn in view of applicant's amendment of the abstract. All previous prior art rejections are maintained.

Claim Objections

Claim 36 is objected to because of the following informalities: "in fluid coupled to" does not make sense. For the purposes of examination, it is assumed that applicant intended to simply recite: "a fixed volume reservoir coupled to ..."

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fram (U.S. Pat. No. 5,540,679).

Regarding claim 1, Fram discloses a method of inflating and deflating a catheter having an expandable membrane, the method comprising the steps of:

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controllably inflating the expandable membrane to a target pressure or volume (col. 5, ln. 64-67 and Fig. 6);

ablating a desired tissue region while maintaining the target pressure or volume of the expandable membrane (col. 1, ln. 45-46, col. 5, ln. 64-67, and col. 6, ln. 4-6);

and controllably deflating the expandable membrane (col. 5, ln. 11-17).

Regarding claim 10, Fram discloses method of claim 1, wherein the step of ablating the desired tissue region is part of a radio frequency ablation process (col. 5, ln. 26-27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fram ('679).

Regarding claim 2, Fram discloses method of claim 1. In addition, Fram discloses heating the balloon up to a preset temperature and deactivating the heating process at any desired time (col. 7, ln. 45-49). Therefore, as a matter of routine skill in the art, it would have been obvious to have kept the expandable membrane inflated until a region proximate the expandable membrane reached a predetermined temperature range and then deflated the balloon once that preset temperature was reached in order to remove the balloon once the procedure was completed.

Claims 3, 6, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fram ('679) in view of Yamaguchi (U.S. Pat. No. 5,433,740).

Regarding claims 3, Fram discloses method of claim 1. The claim differs from Fram in calling for the inflation/deflation control means to be located within a first console. Yamaguchi, however, teaches a control means 18 located within a first console 1 for inflating and deflating a balloon 6 (col. 4, ln. 47-64 and Figs. 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have located the inflation/deflation control means within a first console in view of the teaching of Yamaguchi as an obvious alternate means of better controlling the inflation and deflation of a balloon catheter that is known in the art.

Regarding claim 6, Fram discloses method of claim 1. The claim differs from Fram in calling for the method of if the target pressure or volume is not reached, re-inflating the expandable membrane in order to reach the target pressure or volume.

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Yamaguchi, however, teaches adjusting fluid flow in order to reach the target pressure or volume in order to keep the balloon in intimate contact with the cavity wall and detect leaks (col. 4, ln. 54-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the step of claim 6 in the method of Fram in view of the teaching of Yamaguchi in order to keep the balloon in intimate contact with the cavity wall and detect leaks.

Regarding claim 11, Fram discloses a method for inflating and deflating a catheter having an expandable membrane, the catheter being part of a catheter system including a first console (see rejection of claim 3), a catheter, and an umbilical system coupling the first console to the catheter (see rejection of claim 3), the method comprising the steps of:

controllably inflating the expandable membrane proximate a desired tissue region, the expandable membrane being inflated to a target pressure or volume in order to provide sufficient mechanical force against the desired tissue region (Fig. 10);

ablating the desired tissue region while maintaining the expandable membrane at the target pressure or volume (col. 1, ln. 45-46, col. 5, ln. 64-67, and col. 6, ln. 4-6);

and controllably deflating the expandable membrane (col. 5, ln. 11-17).

The claim differs from Fram in calling for the method to further comprise evacuating air from the expandable membrane by creating a vacuum in the expandable membrane. Yamaguchi, however, teaches evacuating air from the expandable membrane by creating a vacuum in the expandable membrane (col. 6, ln. 47-52).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to have included the step of evacuating air in the method of Fram in view of the teaching of Yamaguchi in order to remove unwanted air from the balloon.

Regarding claims 35, Fram discloses method of claims 1 and 3 in view of Yamaguchi. The claim differs from Fram in calling for the inflation/deflation control means to be a proportional valve for controlling the delivery of fluid in order to reach and maintain a predetermined pressure in the balloon.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fram ('679) in view of Yamaguchi ('740) and further in view of Edwards (U.S. Pat. No. 6,258,087 B1).

Regarding claim 4, Fram discloses the method of claims 1 and 3 in view of Yamaguchi. The claim differs from Fram in view of Yamaguchi in calling for the inflation/deflation control means to be a Proportional Integral Derivative controller. Edwards, however, teaches a pump system that uses a Proportional Integral Derivative controller to control fluid flow (col. 36, ln. 15-20) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a Proportional Integral Derivative controller in the method of Fram in view of Yamaguchi, further in view of the teaching of Edwards as an obvious means of better controlling fluid flow to the balloon that is known in the art.

Regarding claim 5, Fram/Yamaguchi/Edwards disclose the method of claims 1, 3, and 4. In addition, the inflation/deflation control means of Yamaguchi includes a pressure switch that controls an on/off valve.

Claims 3, 9, and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fram ('679) in view of Joye (US PGPub 2002/0045894 A1).

Regarding claims 3, Fram discloses method of claim 1. The claim differs from Fram in calling for the inflation/deflation control means to be located within a first console. Joye, however, teaches a control means 68 located within a first console 78 in order to control the inflating and deflating of balloon 22 (pg. 6, ¶ 49 and Fig. 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have located the inflation/deflation control means within a first console in view of the teaching of Joye as an obvious alternate means of better controlling the inflation and deflation of a balloon catheter that is known in the art.

Regarding claim 9, Fram discloses the method of claim 1. The claim differs from Fram in calling for the step of ablating the desired tissue region to be part of a cryoablation process. Joye, however, teaches a balloon catheter for cryoablation (pg. 1, ¶ 3 and Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have introduced cryogenic fluid into the balloon of Fram in view of the teaching of Joye as an obvious alternate method of using a balloon catheter to treat tissue that is well-known in the art.

Regarding claim 32, Fram discloses the method of claim 1. The claim differs from Fram in calling for the step of controllably deflating the expandable membrane to include preventing deflation until a temperature in the balloon is higher than a predetermined temperature. As stated in the preceding rejection of claim 9, it would have been obvious to use cryogenic fluid in the balloon catheter of Fram in view of

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Joye. Joye further teaches preventing deflation until a temperature in the balloon is higher than a predetermined temperature in order to minimize any potential tearing of the tissue resulting from a frozen cooling balloon adhering to the tissue (pg. 6, ¶ 48). The warning light or audio signal of Joye causes the operator to perform the step of preventing deflation until a temperature in the balloon is higher than a predetermined temperature (0° C), since deflating the balloon is a step that inherently occurs before removing the balloon catheter. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the step of controllably deflating the expandable membrane of Fram to include preventing deflation until a temperature in the balloon is higher than a predetermined temperature in order to minimize any potential tearing of the tissue resulting from a frozen cooling balloon adhering to the tissue.

Regarding claim 33, Fram discloses the method of claim 1. The claim differs from Fram in calling for the step of controllably deflating the expandable membrane to include reducing adhesion between the expandable membrane and the desired tissue region. As stated in the preceding rejection of claim 9, it would have been obvious to use cryogenic fluid in the balloon catheter of Fram in view of Joye. Joye further teaches allowing the balloon temperature to thaw to above 0° C before removing the balloon in order to minimize any potential tearing of the tissue resulting from a frozen cooling balloon adhering to the tissue (pg. 6, ¶ 48). Deflating the balloon is a step that inherently occurs before removing the balloon catheter. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the step of

controllably deflating the expandable membrane of Fram to include reducing adhesion between the expandable membrane and the desired tissue region in view of the teaching of Joye in order to minimize any potential tearing of the tissue resulting from a frozen cooling balloon adhering to the tissue.

Regarding claim 34, Fram discloses the method of claims 1 and 33 in view of Joye. In addition, see the preceding rejection of claim 32.

Regarding claim 35, Fram discloses the method of claims 1 and 3 in view of Joye. The claim differs from Fram in calling for the inflation/deflation control means to be a proportional valve for controlling the delivery of fluid in order to reach and maintain a predetermined pressure in the balloon. As stated in the preceding rejection of claim 9, it would have been obvious to use cryogenic fluid in the balloon catheter of Fram in view of Joye. Joye further teaches a control valve 68 for controlling the delivery of fluid in order to reach and maintain a predetermined pressure in the balloon (pg. 6, ¶ 49 and Fig. 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the inflation/deflation control means of Fram be a valve for controlling the delivery of cryogenic fluid in view of the teaching of Joye in order to reach and maintain a predetermined pressure in the balloon. Finally, applicant has not provided any criticality or unexpected result associated with using a proportional valve that defines over the system of Joye comprising a pressure transducer 23 coupled to a control valve 68 (pg. 6, ¶ 49 and Figs. 10-11).

Regarding claim 36, Fram discloses the method of claims 1 and 3 in view of Joye. The claim differs from Fram in calling for the inflation/deflation control means to

be a fixed volume reservoir coupled to a shutoff valve located within the first console. Joye, however, teaches a inflation/deflation control means that is a fixed volume reservoir 72 coupled to a shutoff valve 68 located within the first console 78 (pg. 5, ¶ 47, pg. 6, ¶ 49, and Figs. 10-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the inflation/deflation control means of Fram be a fixed volume reservoir coupled to a shutoff valve located within the first console in view of the teaching of Joye as an obvious alternate method of supplying and controlling fluid flow to a catheter balloon that is well-known in the art.

Response to Arguments

Applicant's arguments filed March 29, 2006 have been fully considered but they are not persuasive.

Regarding independent claims 1 and 11, the examiner cited col. 5, ln. 64-67 of Fram to establish that the balloon material remains dimensionally stable while ablating tissue. Since the balloon remains dimensionally stable, it is inherently controllably inflated to a target volume. Applicant further argues that the pressure inside the balloon increases as the fluid heats up. While this is true, the balloon still remains dimensionally stable, and therefore at the same target volume. It should be noted that applicant claims inflating the expandable membrane to a target pressure or volume. Finally, applicant argues that Fram does not controllably deflate the balloon. The operator of the device of Fram, however, clearly can choose when to inflate and deflate the balloon for use. This inherently constitutes controllably deflating the expandable membrane because

applicant has not claimed any further steps other than deflating the expandable membrane that are required in the deflation procedure.

Regarding claim 9, the examiner maintains that it would be obvious to one of ordinary skill in the art to use a balloon catheter for either cryoablation or hyperthermic ablation since both types of balloons are well-known in the art. For support, see col. 3, ln. 45-64 and col. 5, ln. 31-41 of Chen (U.S. Pat. No. 6,066,132), which discloses a balloon catheter that can be used with either cryogenic or hyperthermic fluid. The examiner is not suggesting heating cryogenic fluid with the device of Fram as the applicant argues. Rather, the examiner maintains that it is obvious to use a balloon catheter with either cryogenic or hyperthermic fluid since both are well-known means for effecting ablation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*
6/6/06

Michael Peffly
MICHAEL PEFFLY
PRIMARY EXAMINER